

Part 2 – Remarks

This Amendment and Response fully responds to the office action mailed September 19, 2008. A Petition for One Month Extension of Time and the fee therefor accompanies this Amendment and Response. Because January 19 and 20 were federal holidays, the time for response to the September 19 office action is extended to January 21, 2009.

In the September 19 office action, claims 1-9 were rejected under 35 USC 103 as obvious from Rioux (US patent 6,494,855) in view of Anderson US patent 4,813,935); claims 10-16, 19-27, 30-37, 40 and 44-48 were rejected under 35 USC 103 as obvious from Rioux and Anderson and in view of Devonec (US patent 6,290,666); claims 17, 18, 28, 29, 30 and 39 were rejected under 35 USC 103 as obvious from Rioux, Anderson, Devonec in view of Ewers (US patent application 2001/0056273); and claim 1 was provisionally rejected for nonstatutory double patenting over pending claims 1, 16 and 17 of the assignee's co-pending application 10/921,356, filed subsequent to this application.

Reconsideration of these rejections is respectfully requested, in view of the amendments to the claims set forth above in Part 1 and the following comments.

Claims 1, 5, 8-12, 20-27, 30, 31, 33-38, 40, 44, 45 and 47 are pending.

Claim Amendments

The subject matter from the canceled claims has been incorporated in the manner set forth in Part 1 in the pending claims.

Claims 2-4, 6-7, 13-19, 28, 29, 32, 39 and 46 have been canceled. The subject matter in those claims is present in other pending claims. The cancellation of these claims has necessitated the change in dependency of some of the pending claims. In addition, some of the dependent claims have been amended to make their form consistent with the new dependency.

The subject matter added to claim 27 was used in canceled claim 28.

It is submitted that no new subject matter has been added by these amendments.

Obviousness Rejections

I. Reconsideration and withdrawal of the obviousness rejection of independent claim 1 and its dependent claims 5, 8 and 9, based on Rioux and Anderson, is respectfully requested.

As more specifically recited in claim 1, an inflation tube extends from a main body of an indwelling partial-length prostate-type catheter through the orifice of the external urinary sphincter muscle and along the urinary canal in the penis. The inflation tube delivers fluid to expand a balloon in the bladder on a distal (upstream) end of a main body of the catheter. The balloon restrains the catheter against downstream movement into the urinary canal. A coiled section of the inflation tube is located proximally (downstream) of the external urinary sphincter muscle. The coiled section restrains the catheter against upstream movement into the bladder.

Using a coiled section of an inflation tube as a restraint against upstream movement of a partial-length prostate-type catheter into the bladder is not disclosed or suggested by Rioux or Anderson. While both Rioux and Anderson use restraints, neither uses a portion of the inflation tube for that restraint.

Rioux uses an entirely separate catheter tube segment 20 as the downstream restraint against upstream movement, and uses a separate inflation tube only for inflation. Nothing in Rioux teaches or suggests that the inflation tube can be coiled to replace a separate downstream restraint. Instead, Rioux teaches that the separate additional tube segment 20 must be used in addition to the inflation tube. Rioux does not teach or suggest combining two separate, individual functional structures for restraint and inflation, with a single component which achieves both of the two previously-separate functions.

The other prior art of record which relates to anchoring a partial-length prostate-type catheter teaches and suggests the same thing as Rioux teaches and suggests -- a separate inflation tube and a separate downstream restraint are required and each performs its own separate function. See, for example, Whalen 2003/0208183 and Eshel 5,916,195 (or its European counterpart 0 935 977).

The Examiner recognizes that Rioux fails to disclose a coiled section of the inflation tube to achieve the additional function of a downstream restraint against upstream movement. Nevertheless, the Examiner relies on Anderson as "analogous art," because as the Examiner alleges, both Anderson and Rioux "solve the problem of draining urine through unobstructed ureter." Page 3, office action.

Anderson describes a hollow coiled stent 10 placed in the internal passageway 32 of the ureter 30 between the kidney 28 and the bladder 26 to maintain the passageway 32 open (column 4, line 65-column 5, line 2). The stent 10 is hollow to enhance the infusion and/or drainage capability of the kidney. An infusion line 36 may be connected to the stent 10 to infuse the kidney with fluid to compensate for fluid flow restrictions (column 1, lines 65-69). Curl shaped portions 14 and 16 act as restraints.

The purpose of Anderson is to hold open the ureter between the kidney and the bladder. The purpose of Rioux is to hold open the prostatic urethra between the bladder and the external urinary sphincter muscle. The purposes of both Anderson and Rioux is therefore the same, to hold open internal passageways so that natural fluids can drain through those passageways. Anderson and Rioux do not address the problem of achieving two functions, restraint and inflation, by use of a single item, the inflation tube, thereby eliminating extra separate parts of a partial-length prostate-type catheter. Because Anderson and Rioux are addressed to problems which are unrelated to the problems solved by the present invention, Anderson and Rioux are not analogous to the present invention. Analogous art applies when the need or problem in one field of endeavor is such that it would have commanded itself to the inventor's intention in a different field. See MPEP 2141.01(a). In this situation, neither Anderson nor Rioux addresses the issue of achieving two functions, restraint and inflation, by a single item, the inflation tube used in a partial-length prostate-type catheter, to thereby eliminate use restrictions and difficulties, manufacturing difficulties and costs associated with two separate items.

Substituting Anderson's curled restraint 14 or 16 for Rioux's tube segment 20 restraint, as proposed by the Examiner, still results in two separate items, and does

not teach or suggest that the single inflation tube may be made to perform both the inflation and restraint functions. The combination fails to teach that the separate downstream restraint can be eliminated by use of the coiled configuration of the inflation tube.

The Examiner argues that "(a) coiled tube would have performed the same function of anchoring a urinary lumen as taught by Anderson." The Examiner uses this rationale for the basis for combining Anderson and Rioux. See page 4, office action. As stated above, this rationale leads to using a separate coiled section from Anderson to replace the separate downstream restraint of Rioux. The substitution or replacement proposed by the Examiner does not make the single inflation tube do the work of the downstream anchor, as well as performing the inflation functions. The record is absent of any basis for combining Anderson and Rioux to reach the scope of claim 1, leading to the conclusion that Anderson and Rioux have been combined with hindsight based on the applicant's disclosure to formulate an improper obviousness rejection.

Dependent claims 5, 8 and 9 should be patentable for the same reasons as claim 1. In addition, claims 5, 8 and 9 relate to details of structure are not described or suggested in either Anderson or Rioux. Claim 5 relates to a plurality of individually adjacent coils, but Anderson describes only a single curl as the restraint. Claims 8 and 9 relate to details of structural width which are not described or suggested in Anderson or Rioux. The Examiner engages in unsupported assumptions concerning structure of a proposed combination of Anderson and Rioux in rejecting claims 8 and 9, because there is no basis in either reference to support those assumptions. Lacking any basis to support the assumptions, the rejection of claims 8 and 9 must be based on the impermissible use of hindsight gained from the present disclosure.

II. Reconsideration and withdrawal of the obviousness rejection of claims 10-12, 20-27, 30-32, 34-38, 40, 44, 45 and 47 based on Rioux, Anderson and Devonec is respectfully requested.

Claim 34 is an independent claim which includes essentially the same subject matter described above in connection with claim 1. Claims 35-38, 40, 44, 45 and 47 depend on claim 34. Claims 10-12, 20-27 and 30-32 depend on claim 1. Because the subject matter of claim 1 is believed to be patentable, for the reasons described above and others, the remaining pending claims should also be patentable.

Claims 10-12, 20-27, 30-32, 34-38, 40, 44, 45 and 47 recite an insertion tool in conjunction with a partial-length prostatic-type catheter defined in claim 1. The rejection relies on Devonec for the alleged obviousness of the claimed insertion tool.

The combination of Rioux, Anderson and Devonec does not explain how such a combination should be used, beyond the simple, non-specific description in Rioux that a "pusher" can be used to "advance the prosthesis up the urethra and into the bladder." (Column 9, lines 25-26) Accordingly, the details of use of the combination of Rioux, Anderson and Devonec are governed by the explanation in Devonec itself, and that explanation does not meet or comply with the subject matter defined in claims 10 and 34 and their dependent claims 11-12, 20-27, 30-32, 35-38, 40, 44, 45 and 47.

Devonec discusses a pusher 63 into which an internal mandrel 61 is inserted. The mandrel 61 extends completely through the pusher 63 and a partial-length catheter 2. The mandrel 61 holds a collapsible section 8 of the catheter 2 in an expanded position, to make the entire catheter 2 including the collapsible section 8 sufficiently rigid so that it can be pushed by the pusher 63. The partial-length catheter 2, the mandrel 61 and pusher 63 are inserted through the urinary canal (Fig. 9). The mandrel 61 is thereafter removed (Fig. 10). The pusher 63 is then removed (Fig. 11), apparently by simply withdrawing the pusher 63 (column 6, lines 59-60). A string 14 is then pulled to retract the partial-length catheter to the point where the collapsible section 8 is located at the external urinary sphincter muscle 5 (Fig. 12).

Devonec discloses an internal coil 52 used to reinforce the portion of the catheter which is upstream of the external urinary sphincter muscle. The coil 52 prevents collapse of this upstream portion of the catheter which extends through the prostatic urethra, such as might occur from pressure from the prostate gland due to BPH or other disease. The mandrel 61 appears to extend through this upstream portion of the catheter, although the pusher 63 does not.

Claims 10 and 34, as well as their dependent claims, recite in the manner set forth, that the insertion tool extends through the downstream restraint-coiled section of the inflation tube when the insertion tool and the catheter are connected together.

The Examiner alleges that Devonec describes an insertion tool which extends through the claimed coiled section of an inflation tube. The coiled section of the inflation tube recited in claims 10 and 34 is located downstream of the external urinary sphincter muscle. The coiled reinforcing section of the Devonec catheter is located upstream of the external urinary sphincter muscle. The two coiled sections are located in entirely different positions. Because Devonec provides the only guidance for use of the alleged combination of Rioux and Anderson, and because that guidance does not comply with or meet the scope of claims 10 and 34, and their dependent claims 11-12, 20-27, 30-32, 35-38, 40, 44, 45 and 47, the alleged combination of Rioux, Anderson and Devonec does not meet the scope of these claims. Accordingly, the subject matter of these claims cannot be rendered obvious by Rioux, Anderson and Devonec.

Claim 34, and dependent claims 35-38, 40, 44, 45, 47, and 22-27, recite a separable connection which permit separation of the main body from the end surgeon tool in response to proximal movement of the insertion tool when the expanded balloon restrains the main body of the catheter against distal movement. Devonec does not describe an expanded balloon, and therefore cannot describe the concept of disconnecting a separable connection in response to downstream movement when restrained by a balloon. Because Devonec does not describe such functionality, there is no description of such functionality with respect to the combination of Rioux and Anderson, because neither of those references also describe such functionality.

Furthermore, there is no apparent suggestion in any of the three references of the disconnection of a separable connection in response to downstream movement of the insertion tool when the main body of a partial-length catheter is restrained by an expanded balloon in the bladder. Lacking such a teaching or suggestion, the combination of Rioux, Anderson and Devonec was formulated with impermissible hindsight based on the present disclosure. The obviousness rejection is therefore inappropriate.

Claims 31 and 47 relate, in the manner specifically set forth therein, to the use of the coiled section of the inflation tube to maintain the inflation tube in alignment with the insertion tool. Because Devonec's coiled section relied on in the obviousness rejection is upstream, it can play no role in aligning the inflation tube with the insertion tool, because the inflation tube extends downstream from the location of Devonec's coiled section. Again, the Rioux, Anderson and Devonec combination fails to meet the scope of these claims.

Claims 25-27 and 35-38 describe, in the manner specifically set forth therein, a selectively disconnectable bridging structure which fastens the catheter main body and the insertion tool. Devonec, which is the only reference of the combination relevant to this feature, has no selectively disconnectable bridging structure, no fastening capability and certainly no separable connection. The end of Devonec's pusher 63 abuts against the end of the catheter with no connection or fastening capability whatsoever. Abutting contact, which is not fastening or connection, is all that is achieved in Devonec and even that requires the mandrel 61 to be in place. Devonec certainly fails to discuss or suggest any bridging structure which fastens pieces together. The combination of Rioux, Anderson and Devonec fails to meet the scope of these claims.

Claims 26, 27 and 36-38 further recite, in the manner set forth specifically therein, a cord which is part of the selectively disconnectable bridging structure. Devonec does not describe a cord which is a part of a selectively disconnectable bridging structure, so the combination of Rioux, Anderson and Devonec likewise fails to describe such a cord and therefore fails to meet the scope of these claims.

Claims 27 and 38 further recite, in the manner set forth specifically therein, that the cord extends through an interior channel of the insertion tool. Claim 38, but not claim 27, has been rejected as obvious from Rouix, Anderson, Devonec and Ewers. Ewers discloses a thread used to hold an upstream anchoring element in a collapsed state while the catheter is inserted. Once inserted, the thread is released so that the upstream anchoring element expands in the bladder. The thread described in Ewers interacts with completely different elements than those recited in claims 27 and 38, and that interaction is for completely different purposes. The combination of Rioux, Anderson, Devonec and Ewers again fails to meet the scope of the claims.

The other pending dependent claims are further distinguishable from the combination of references cited by the plain language of those claims themselves.

For the reasons set forth above, and others, it is believed that the obviousness rejections based on Rioux, Anderson, Devonec and Ewers fail to meet the scope of the claims and/or are based on the impermissible use of hindsight, because there is no evidence of record to indicate that a person having ordinary skill in the art would combine the references as alleged by the Examiner. Withdrawal of the obviousness rejections is appropriate and requested.

Nonstatutory Double Patenting Rejection

This provisional rejection applies with respect to the alleged similarity to claims 1, 16 and 17 of application serial number 10/921,356. Claims 1 and 17 of application 10/921,356 have been canceled from that application. Claim 16 has been amended to depend on another claim in that application which has not been asserted as a basis for nonstatutory double patenting of this application. Accordingly the nonstatutory double patenting rejection of this application should no longer applicable and should be withdrawn.

Conclusion

For the reasons set forth above, and others, the pending claims define patentable subject matter which is not obvious over the cited references. Allowance of the pending claims is respectfully requested.

If the Examiner still regards any of the pending claims as not patentable, the courtesy of a telephone call to the undersigned is requested.

Respectfully submitted,

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